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APPLICATION NO. 18M1/0804	FILING DATE 08/04/97	HARRISON	FIRST NAMED INVENTOR	L	18300	ATTORNEY DOCKET NO.
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18M1/0804

SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY NY 11530

VANDEVEEST F
EXAMINER

1816	PAPER NUMBER
ART UNIT	

08/04/97 6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/663,272

Applicant(s)
Harrison, L, et al.

Examiner
F. Pierre VanderVegt

Group Art Unit
1816



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with the Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-36 are currently pending in this application.

This application contains sequence disclosures that are encompassed by the definitions
5 for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 CFR 1.821 through
1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For
Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence
Disclosures. There has been no computer readable form submitted with this application.

10 Applicant is also reminded that the sequence rules apply to nucleotide sequences which appear
in the claims, the written disclosure and the Figures/Drawings. It is noted that this application
contains disclosure of amino acid sequences in the drawings which are not in conformance
with the sequence requirements.

Election/Restrictions

- 15
1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so
linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to
20 elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-29 and 36, drawn to a recombinant GAD-65 or proinsulin peptide, a
method of assay using the peptide and a composition classified in class 530,
subclass 350 and class 435, subclass 7.1.

25 Group II, claim(s) 30-35, drawn to a method of treatment with a recombinant GAD-65 or
proinsulin peptide classified in class 514, subclass 12.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept
30 under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

technical features for the following reasons: The method of Group II entails the administration of peptide to a subject in vivo, while the method of Group I is an in vitro procedure which examines the reactivity of isolated T cells to said peptides.

5 3. A telephone call was made to Mr. Peter Bernstein on July 25, 1997 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Conclusion

5. Papers related to this application may be submitted to group 1800 by facsimile transmission. Papers should be faxed to group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 20 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1816 is (703)305-3014. *Communications which are not to be entered into the record, such as proposed amendments, should be clearly marked "DRAFT" and faxed to (703)305-7939.*

Any inquiry concerning this communication or earlier communications from the examiner 25 should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should 30 be directed to the group 1800 receptionist, whose telephone number is (703)308-0196.

July 30, 1997
F. Pierre VanderVegt, Ph.D.


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☒ 7.
Other: SEQUENCES ARE DISCLOSED IN THE SPECIFICATION/DRAWINGS WHICH ARE
NOT INCLUDED IN THE SEQUENCE LISTING

Applicant must provide:

☒ An initial ~~or substitute~~ computer readable form (CRF) copy of the "Sequence Listing"

☒ An ~~initial or~~ substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.